

REMARKS

Claims 1-20 are pending in the application. Claims 11-20 have been canceled. Claims 1-10 have been amended for the purpose of clarity and to conform to U.S. patent practice. Claim 21 has been added. Reconsideration and allowance of Claims 1-10 and 21 in view of the above amendments and following remarks is respectfully requested.

Objection to the Specification

The specification has been objected to because the Abstract does not begin on a separate sheet. The specification has been amended to comply with this requirement. The Abstract has also been amended. In view of the amendments, withdrawal of the rejection is requested.

The Rejection of Claim 6 Under 35 U.S.C. § 112, First Paragraph

Claim 6 has been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Withdrawal of the rejection is requested for the following reasons.

The Examiner believes that the term "dielectric material" in Claim 6 is not described in the specification in such a way as to convey to the skilled person that the inventors had possession of the claimed invention at the time the application was filed. The Examiner notes that although the term is mentioned in the specification, the term is not defined and that because there is a single preferred example for the material, the Examiner states that the specification does not support the use of the term "dielectric material."

Applicants believe that the term is well defined in the specification. At page 6, last full paragraph, the specification refers to dielectric material as a material that, "when exposed to microwaves, increases in temperature in proportion to power applied."

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Because the specification as originally filed does convey to the skilled person that applicants had possession of the invention as claimed, applicants submit that the written description requirement has been met. Withdrawal of the rejection is respectfully requested.

The Rejection of Claims 1-10 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-10 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Withdrawal of the rejection is requested for the following reasons.

The Examiner has objected to the term "massively" in Claim 1 and states that the term is relative and therefore renders the claim indefinite. Claim 1 has been amended to delete the term "massively."

The Examiner has objected to the term "it" in Claim 1. Claim 1 has been amended to delete the term "it." Applicants believe that the amendment makes clear that it is the drug that is present in amorphous form.

The Examiner believes that the phrase "present in amorphous form in a quantity greater than or equal to 50%" in Claim 1 renders the claim indefinite. Claim 1 has been amended to make clear that the drug is present in an amorphous form in a quantity greater than or equal to 50% and that the remaining percentage is the percent of residual crystallinity of the drug.

The Examiner believes that the phrase "loaded with" in the context of "polytetrafluoroethylene loaded with graphite" in Claim 7 renders the claim indefinite because it is not clear what the structural or chemical relationship is between polytetrafluoroethylene and graphite.

The term "sparingly" in the context of "a drug sparingly soluble in water" in Claim 10 is considered by the Examiner to render the claim indefinite.

The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the

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specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). Applicants believe that the phrase "loaded with" in Claim 7 and the term "sparingly" in Claim 10 are definite because the skilled person would understand the meaning of the claims that include these terms, when the claim is read in light of the specification.

Applicants submit that the skilled person would understand the meaning of the phrase "loaded with" in the context of "polytetrafluoroethylene loaded with graphite" to be that the polymer is charged with particles or powders of a solid substance (e.g., an inorganic substance). The term can be found in numerous U.S. patents (e.g., U.S. Patent Nos. 6,92,467; 7,250,454; 7,255,895; and 7,335,623) as well as in the scientific literature (e.g., "Fully Flexible Terahertz Bragg Reflectors Based on Titania Loaded Polymers," C. Jansen et al., Conference on Lasers and Electro-Optics (CLEO), San Jose, CA, May 4, 2008; or "Electron Microscopy of Carbon-Loaded Polymers," V.E. Hanchett et al., <http://www.research.ibm.com/journal/rd/274/ibmrd2704T.pdf>). Accordingly, withdrawal of this grounds for rejection is respectfully requested.

Applicants submit that the skilled person would understand the meaning of the term "sparingly" in the context of "a drug sparingly soluble in water." The term can be found in the claims of numerous U.S. patents (e.g., U.S. Patent No. 7,223,419, Claim 1; U.S. Patent No. 7,189,415, Claim 1; and U.S. Patent No. 7,153,520, Claim 1). In view of the commonality of this term and its acceptance in the art, Applicants submit that the term "sparingly" is definite because the skilled person would understand the meaning of the claim that includes this term, when the claim is read in light of the specification. Accordingly, withdrawal of this grounds for rejection is respectfully requested.

In view of the amendments to the claims and the foregoing remarks, withdrawal of the rejection is respectfully requested.

The Rejection of Claims 1-3 and 6-10 Under 35 U.S.C. § 102(b)

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Claims 1-3 and 6-10 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Bergese et al. (Materials Science and Engineering). Withdrawal of the rejection is requested for the following reasons.

The Bergese reference, entitled "Microwave Generated Nanocomposites for Making Insoluble Drugs Soluble," co-authored by inventors Columbo and Gervasconi, was published in 2003. The present application claims priority to Italian Application No. MI2002A002748, filed December 23, 2002. Because the claimed invention is fully supported by the priority application and the present application is entitled to the benefit of the priority date, the Bergese reference is not citable as prior art against the claimed invention.

Attached hereto as **Exhibit A** is the English language translation of the Italian priority document, Italian Application No. MI2002A002748, filed December 23, 2002. Exhibit A also includes the declaration of Giovanna Luisa Sarolo pursuant to 37 C.F.R. § 1.68, declaring that the English translation is complete, accurate, and fairly reflects the meaning and content of the Italian language document.

The application describes mixing the drug and organic carrier, applying an oscillating electromagnetic field to increase the temperature to a temperature greater than the melting point of the drug, and maintaining that temperature for the recited period of time to provide the recited composite having the recited characteristics. Applicants note the following passages from Tables 1-8 of the priority application, which describe heat treatments of compositions achieved by modulating the microwave irradiation:

Table 1, Sample Beta/Ibu13, from 25 to 90°C in 15 minutes, followed by 10 minutes at 90°C;

Table 1, Sample Beta/Ibu14, from 25 to 90°C in 15 minutes, followed by 20 minutes at 90°C;

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Table 2, Sample PVP/Ibu01, from 25 to 90°C in 15 minutes, followed by 10 minutes at 90°C;

Table 2, Sample PVP/Ibu02, from 25 to 90°C in 15 minutes, followed by 15 minutes at 90°C;

Table 3, Sample PVP/Nim01, from 25 to 160°C in 20 minutes, followed by 10 minutes at 160°C;

Table 3, Sample PVP/Nim03, from 25 to 160°C in 20 minutes, followed by 20 minutes at 160°C;

Table 4, Samples PVP/Nim01 and PVPO/Nim02, from 25 to 150°C in 20 minutes, followed by 10 minutes at 150°C;

Table 5, Sample PVP/Nif02, from 25 to 175°C in 15 minutes, followed by 10 minutes at 175°C;

Table 6, Sample PVP/Nim05, from 25 to 150°C in 10 minutes, followed by 20 minutes at 150°C;

Table 6, Sample PVP/Nif04, from 25 to 175°C in 15 minutes, followed by 10 minutes at 175°C;

Table 7, Sample PVP/Nim07, from 25 to 155°C in 10 minutes, followed by 10 minutes at 155°C; and

Table 8, Sample PVP/Nim06, from 25 to 150°C in 10 minutes, followed by 15 minutes at 150°C.

Because the claimed invention is fully supported by the priority application and because the present application is entitled to the benefit of the priority date, the Bergese reference is not citable as prior art against the claimed invention. Withdrawal of the rejection is respectfully requested.

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The Rejection of Claims 1-10 Under 35 U.S.C. § 103(a)

Claims 1-10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over by Bergese et al. (Materials Science and Engineering) in view of WO 97/06781, Miyamoto et al. Withdrawal of the rejection is requested for the following reasons.

As noted above with regard to the Section 102(b) rejection, the Bergese reference is not citable as prior art against the present invention. Because the Section 103(a) rejection is premised on the Bergese reference, applicants submit that the Section 103(a) rejection is also improper. Withdrawal of the rejection is respectfully requested.

New Claim 21

Claim 21 has been added. Claim 21 depends from Claim 1 and recites specific complexing agents. Support for the Claim 21 can be found throughout the specification as originally filed.

Conclusion

In view of the above amendments and foregoing remarks, applicants believe that Claims 1-10 and 21 are in condition for allowance. If any issues remain that may be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicants' attorney at 206.695.1755.

Respectfully submitted,

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